

THE STUDY OF THE ROLE OF DIGITAL TRANSFORMATION ON
THE PHARMACEUTICAL MANUFACTURING PROCESS IN THE
NIGERIAN PHARMACEUTICAL INDUSTRY.

Research Dissertation presented in partial fulfillment of the requirements for the degree
of

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August 2021

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I certify that the dissertation entitled:

The study of the role of Digital Transformation on the pharmaceutical manufacturing process in the Nigerian Pharmaceutical Industry

submitted for the degree of **MSc in Pharmaceutical Business and technology** is the result of my own work and that where reference is made to the work of others, due acknowledgment is given.

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ABSTRACT

In this dissertation, an exploration of the role of digital transformation in the Nigerian pharmaceutical manufacturing industry was studied. The study was constructed around descriptive primary exploratory research design and a qualitative research method was used in achieving a robust understanding of the relevance of digital transformation and various advanced digital tools in a pharmaceutical manufacturing operation in the wake of the recent industrial 4.0 revolution and hence pharma 4.0 concept which entails being smart and efficient in achieving manufacturing excellence.

To achieve this aim, a purposive snowballing sampling technique was used in enlisting Ten (10) pharmaceutical industry experts who are familiar with pharmaceutical manufacturing operations and knowledgeable on the various industrial developments around them. Using mobile phone calls, five (5) separate in-depth semi-structured interviews were successfully conducted with the five of the experts who were sourced from different secondary drug-producing companies in Nigeria. In the interviews conducted, sixteen (16) questions, formulated through inductive reasoning, were used as a guide and all responses were audiotaped, transcribed into text equivalent, and analyzed using thematic content analysis.

In the analysis of the interview data, six major themes were identified and discussed. The study found out that while there is an awareness of the concept of digital transformation in the Nigerian pharmaceutical industry environment, the industry is nevertheless “digitally immature” as the manufacturing process is exclusively driven by traditional. It is as well found out in the study digital transformation comes with the potential to achieve operational excellence (measured in term of reduced waste, decreased error/batch defect rate, improved product quality, less equipment downtime, etc.) and contribute to business excellence by positively impacting the business model of pharma companies in Nigeria which is based on speed to market and competitive pricing that requires efficient production and effective cross-functional supply chain integration). While these were identified as some of the endless potentials of digital transformation in pharma manufacturing, cultivating a digital mindset was found to be an integral initiative in achieving digital transformation in the Nigerian manufacturing industry environment which is not free of challenges. Factors including poor infrastructural developments, lack of investment and resources were identified as “general barrier/challenges” while factors including knowledge gap, lack of expertise, and regulatory hurdles were identified as “industry-specific barriers/challenges” faced by Nigerian pharmaceutical companies in embracing pharma 4.0 model and achieving digital transformation and hence making the industry to be digitally immature.

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CHAPTER ONE: INTRODUCTION

1.1. Research Background

As defined by Schwertner (2017), digital transformation is the application of advanced information-driven technology to build new business models, processes, software, and systems that result in greater competitive advantage, higher operational efficiency, and more profitable revenue for businesses. The concept of digital transformation, conceptualized as the characteristic feature of industrial 4.0, has sparked a significant industrial revolution causing businesses to digitize their concepts and processes and adapt digital tools to their operations. In the manufacturing sector, process dynamism is changing and the application of some of these advanced digital technologies to various manufacturing process operations has become the dominant practice in enabling process optimization and operational excellence (Lee, Cameron, and Hassall, 2019). The new norm is that companies are now improving their operations through a set of emerging technologies (tools and processes) that are enabling smart, decentralized production via intelligent factories, integrated IT systems, the Internet of Things, and flexible, highly integrated manufacturing systems (Ehrhardt and Behner, 2016). The novelty of digital transformation goes a long way for manufacturing firms as it comes with the avenue to make improved changes to manufacturing processes in terms of informatization of production process, customization of products, networking of production line as well as increased production efficiency among others (Wang et al., 2011). Thus, a digitally transformed manufacturing environment can contribute to overall process excellence through streamlined equipment dispersion and control independence as well as intelligent connection courtesy of informatization process which enables the organic combination of human resources, machines, and raw materials in their manufacturing environment (Wang et al., 2011, Monostori, 2014).

The pharmaceutical industry operates in a tightly regulated environment and unsurprisingly one of the most rigid industries which hardly make changes to the way processes are being carried out. The recent pace change across industries has accelerated the adoption of digital technologies and executives across industries are executing digital transformations as part of their corporate strategies (Ehrhardt and Behner, 2016; Liu and Xun, 2017). The first wave of the digital transformation in the pharmaceutical industry centered around the use of technology platforms and data analytics to better understand patients to increase patient engagement and develop new go-to-market approaches (Ehrhardt and Behner, 2016). Despite the industry's cautious reluctance

to make changes to the product manufacturing process and adopt digital technologies to improve manufacturing processes, the next wave of the digital revolution in the pharma environment is tending towards transforming operations (Ehrhardt and Behner, 2016). The adoption of digital technologies in transforming pharmaceutical processes has a wide array of advantages when the increasing rate of change and challenges including process complexity, price and cost pressure, and market demand for personalized medicine, among others are taken into consideration (Landwehr. 2015; Ehrhardt and Behner, 2016). Digitization thus holds tremendous potential in helping companies adapt as industry and market dynamism change.

1.2. Research Purpose

The pharmaceutical industry is one of the most tightly regulated industries in the world and is well known for rigidity when it comes to the adoption of technologies in improving process operations. Manufacturing operations in the pharmaceutical industry still rely on the same old paradigm which has been around for some time and firms base their competitive advantage around massive product development while focusing less on process optimization. Experts have discussed the role that digital transformation can play in any manufacturing environment with the adoption of digital technologies earmarked to be novel in achieving excellent operations (based on judicious use of resources) and as well be a source of competitive advantage. For instance, it is understood that digital transformation of production processes has the potential to contribute to cost reduction and improve operations when testing and releasing new products. Industry experts have discussed the digital transformation of processes to be essential if pharmaceutical firms are to rise to the challenge of increasingly competitive price (and therefore cost) pressures by being more efficient operations in their operations (Ehrhardt and Behner, 2016).

With pharmaceutical industry experts and scholars having discussed, from a different frame of reference, the role that digital transformation can play in pharma industry environments, this study intends to explore the role it can play manufacturing line of companies whose competitive advantages are based around product manufacturing and price competition which in most cases require an optimum and organic combination of human resources, materials and equipment/machines.

1.3. Significance of the Study

As the concept of digital transformation of manufacturing operation has been gaining significant attention in the pharmaceutical industry environment, this study intends to achieve an understanding of the relevance of the adoption of digital technologies in the Nigerian pharmaceutical industry environment which is dominated by secondary pharmaceutical companies whose manufacturing operations centers majorly around the combination of APIs and excipients into dosage products.

This research strives to understand why digital transformation has been earmarked as a source of competitive advantage through which excellent pharma manufacturing operations can be achieved and enabling pharma companies to build a competitive advantage with their resources. The overarching intent of the study is linked to several practical outcomes which will prove to be significant in making various assertions and hence recommendations to pharma industry leaders on the novelty of digital transformation in the manufacturing line.

One of the practical outcomes would be reflected in gaining firsthand knowledge on the digital maturity in the Nigerian pharmaceutical industry, the industry's preparedness for the new wave of change in the pharma environment, and as well achieve a robust understanding of how the adoption of digital technologies can contribute to process improvement and hence operational excellence all of which can amount to competitive advantage in the characteristic Nigerian pharmaceutical industry environment like all other around the world which is known for price competitiveness. Also, the research will prove to be theoretically significant in contributing to the growing list of knowledge detailing digital transformation in the pharmaceutical industry environment.

1.4. Research Aim and Objectives

This research aims to explore the potential role of digital transformation on pharmaceutical industry manufacturing process operations and how this can contribute to operational excellence for pharmaceutical companies in the Nigerian environment. To study and achieve this aim, the following set of targeted objectives are intended to be realized within the scope of the dissertation are summarized in Table 1

Table 1: Research Objectives and Research Questions

S/N	Research Objective	Research Questions
1	To study the current level of digital maturity in the Nigerian pharmaceutical industry environment	<ul style="list-style-type: none"> • What is digital transformation? • What is the level of digital maturity in the Nigerian pharmaceutical industry environment?
2	To assess the Nigerian pharmaceutical industry preparedness for the new pace of change that has to do with the adoption of digital technologies in manufacturing operations	How are pharmaceutical industry leaders responding to the new pace of industrialization that has to do with the use of digital technologies in manufacturing operations?
3	To explore the key areas of manufacturing processes in which digital technologies can be of relevant adoption and how the application of digital technologies can translate to operational excellence	<ul style="list-style-type: none"> • In what areas of pharmaceutical manufacturing operations can digital technologies find relevant applications? • What are the specific digital technologies that can be adopted in manufacturing floor activities? • How can the use of specific digital technologies in the manufacturing floor activities contribute to operational excellence?
4	To Study the potential impact of Digital transformation on Nigerian pharma industry business model and strategies	<ul style="list-style-type: none"> • How will digital transformation affect the business and corporate strategy of Nigerian pharma companies? • What role will digital transformation in product price and speed to market?
5	To assess the specific barriers to the adoption of digital technologies in the manufacturing process in the Nigerian pharmaceutical industry	What are the general and industry-specific barriers to the adoption of digital technologies in the Nigerian pharmaceutical industry?
6	To suggest ways through which pharmaceutical companies can best position themselves for digital	How can Nigerian pharmaceutical companies best overcome any barriers to digital transformation in process operations

	transformation and overcome potential barriers in adopting digital technologies in manufacturing operations.	
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1.5. Methodology

To achieve the aim and smart objectives of the research, a qualitative research method paradigm is followed. This research paradigm is in line with a designed study that intends to achieve an understanding of a research concept by leveraging the use of in-depth interviews to collect data that is grounded in reflective opinions and experiences of experts about the concept being studied (Saunders et al., 2009). Also, the research paradigm entails the incorporation of human elements into the study as it cannot be independently carried out through observations. In this regard, an interpretivism research philosophy and inductive research approach are adopted for this study to enable the inclusion of the human element into the study plan to facilitate a way through which experts and leaders in the Nigerian pharmaceutical industry can be engaged with series of semi-structured interview questions that are developed through the inductive reasoning

Therefore, primary qualitative data would be generated and used in achieving the aims and smart objectives of the study. To achieve this, the research will draw its strength from the use of a semi-structured interview strategy which combines both the use of structured and unstructured questions and facilitate an avenue for the experts to freely explain their quality-rich subjective and objective opinions based on a diverse range of questions about the Nigerian pharmaceutical industry environment and the role that that digital transformation can play in their various process operations. From the analysis of the quality-based data collected from the interviews, it will be convenient to discern specific areas in which digital technologies are finding significant application

1.6. Structure of the Study

This dissertation is structured into five major chapters The first chapter captures and projects the introductory aspect of the research work by detailing the research background, its purpose and significance of the study as well as the aims and smart objectives to be achieved. Also, this chapter gives a broad overview of the research method

Chapter two with its various headings and subheadings details the extensive and robust review of the works of literature that capture the pharmaceutical industry environment and the new norm of digital transformation which has given rise to the popularity of industrial 4.0 and hence pharma 4.0 in the context of the pharmaceutical industry.

Chapter three henceforth called methodology captures and projects the research method in terms of the adopted philosophy, approach, and strategy being used in collecting the research data. The chapter also gives an insight into the qualitative data analysis method

Chapter four of the dissertation contains the research findings and results of the analysis carried out while chapter five of the dissertation summarizes the research carried out and

explains the theoretical and practical implications of the findings established in chapter four. Also, supplementary recommendations are made along with improved suggestions for any potential future research in this chapter.

CHAPTER TWO: LITERATURE REVIEW

2.1. Overview

This chapter is a holistic review of the literature and various publications that center around the concept of industrial 4.0 and how it relates to manufacturing processes and is contextually relevant to the pharmaceutical manufacturing environment (hence pharma 4.0). An appraisal of the role and relevance of the concept, its enablers are carried out in this chapter and the identified knowledge gaps to be bridged are discussed.

2.2. Industry 4.0—The Paradigm of Digital Transformation

The industrial landscape is highly subjected to change and one of the most revolutionized as there have been four major industrial revolutions characterized by the use of different approaches and technologies in production processes. Starting with the industrial era 1.0 involving the use of mechanization and steam power that is at the heart of industrial operations, there have been three other successive industrial revolutions including the era of mass production and assembly line (industry 2.0); the era of automation, computer and electronics (industry 3.0) and now the era of cyber-physical systems and networked advanced technologies (industry 4.0) (see fig 1). Researchers have used the term “factory of the future” to describe this new age of industrial revolution which enables the digitalization and interconnection of distributed manufacturing entities in a ‘system of systems’ approach (Borangui et al., 2020). According to the International Electrotechnical Commission (2018), the factory of the future is a highly connected and adaptive system in which new types of production resources will be highly interconnected and self-organizing in the entire value chain. In the same vein, another novel possibility in the factory of the future is that process will be driven by decision making based on data made available from real-time processes.

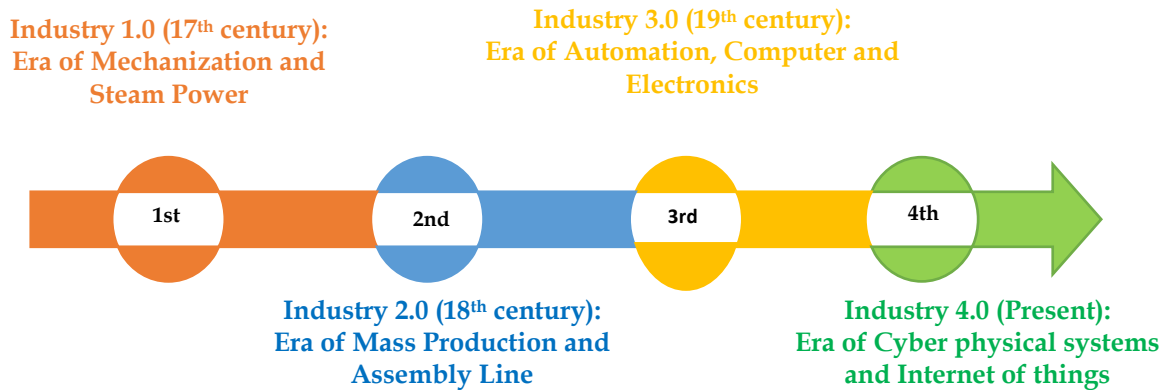


Figure 1: Industrial Revolutions timeline

The term industrial 4.0, introduced by the Germans, has been used to capture the new industrial landscape characterized by the use of smart technologies to drive the various industrial business operations. Researchers have also used other terms including intelligent manufacturing (China), advanced manufacturing (United States) as well as e-factory (Japan) to describe this new wave of industrial revolution indicating the new form of manufacturing systems highly regarded to be adaptive, automatized, analytical and highly efficient stemming from the use of advanced integrated information, communication, and control technologies (ICCT) and intelligent devices (Borangui et al., 2020). It has been stressed further that an integral component of the concept is the Internet of Things (IoT), which comes with the possibility to establish intelligent machine-to-machine connectivity within and beyond the walls of any manufacturing enterprise. In this regard, physical assets such as smart robots have been described as tools, enabling flexible pre-configuration on-the-fly and modular replacement of resources (Gaertner, 2015). With these series of possibilities, the idea behind Industry 4.0 can simply be summed up as an initiative aimed at connecting human resources, data, and physical machines in a cyber-physical network and hence making a part or all aspects of an organization be digitally transformed.

2.3. Business Excellence and Digital Transformation

Digital transformation in the manufacturing firm environment has been described by various experts, researchers, and scholars alike to be potential in contributing to business excellence. The effect of digital transformation in the manufacturing environment has been described to be pronounced in three major areas including efficient product development, efficient manufacturing, and more sophisticated products and services in well-integrated and coordinated value chains in an enterprise (Bjorkdarhl, 2020).

2.3.1. Digital Transformation and Product Development

In the areas of product development, digitalization has the potential to make manufacturing firms' product development more efficient as digitalization of product development activities reduces the need for physical artifacts and prototypes by making the use of interactive computer-based design, product visualization as well as numerical computation programs which makes product design much easier (Bjorkdarhl, 2020). With digital technologies, manufacturing can develop more sophisticated products by integrating technologies into them and hence making them more intelligent. A typical example of this trend is seen in the development of sophisticated wearable medical devices (e.g. wearable blood pressure monitors, ECG monitors, biosensors) which collect the health data of patients without affecting their daily routine. The resultant product performance data generated while the product is in use may help the firm increase performance or give rise to new functionalities.

Also, Porter and Heppelmann (2014) explained that the integration of digital technologies allows the firm and its customers to collect valuable data on the product and applications that depend on that product, thereby enabling collaboration in monitoring products performance for effective optimization and improvements. The implication of making traditional products more "intelligent" and sophisticated has been described as making any manufacturing enterprise move downstream and provide new operational and complementary services which translate to a new source of competitive advantage for manufacturing enterprises, increasing business revenue streams and hence the increase in overall profitability (Bjorkdarhl, 2020). The endless possibilities of digital transformation in product development have also been to be pronounced in product testing. Testing is an important part of a firm's product development activities and as demand for shorter development times increases for manufacturing enterprises, product testing in

ascertaining the performance and functionality of the product (before actual development and launch) can be achieved within an appreciable time frame with the use of digital technologies and software that are packed with specific models.

2.3.2. Digital Transformation and Manufacturing Excellence

Digital transformation enables manufacturing enterprises to foster a new form of manufacturing system described by Borangui and colleagues (2021) as digital manufacturing whose environment is characterized by the presence of smart embedded devices working together seamlessly via the internet of things (IoT), that enables the centralized system controls to be transferred to networks of distributed intelligence based on machine-to-machine (M2M) connectivity at shop-floor level. The general overarching goals of industry 4.0 development have been stated to include achieving:

- Efficient control of complex distributed systems as an autonomous unit;
- Enabling the Integration of the physical world with the virtual world which is an advanced platform where physical elements including sensors, products, material processing, handling, and transport resources and human operators are represented by a software unit in CPPS;
- Optimizing decision making and efficiency (cost-effectiveness, high performance, and energy saving);
- Creating new business models and service-oriented approaches to value creation.

(Borangui et al., 2020)

In the areas of manufacturing processes, digital transformation has been said to confer a competitive advantage to manufacturing firms by enabling increased throughput and quality, decrease variance, and minimize the number of breakdowns, stoppages, and operational bottlenecks by making the manufacturing process more intelligent through the use of digital technologies and more and better data (Bjorkdarhl, 2020). Computer visualization systems that use machine learning algorithms to identify defects in the manufacturing process have been said to be novel and significant applications in reducing the traditional need to take products or materials out of the production line and check them manually as inspection becomes online and in real-time. The advantage of this is that manufacturing enterprises can be as lean as possible

and more efficient in the use of manufacturing resources. Even with the “digital twins” or model of the overall product manufacturing process being retained in the cloud system of a manufacturing enterprise, process improvement can be achieved based on the performance of the product in a live setting (Haag and Anderl, 2018). This has been said to be a source of competitive advantage in a manufacturing environment as enterprises can boost superior manufacturing capacity that is based on continuous improvement (Haag and Anderl, 2018; Bjorkdarhl, 2020). With equipment breakdown being one of the leading contributors to an operational bottleneck in the manufacturing line, predictive maintenance with the use of AI-enhanced predictive tools including accelerometers, digital sensors, and advanced software algorithms allows reporting of the machines’ real-time conditions leading to optimized equipment efficiency at lower maintenance and inspection cost (Zhang et al., 2019).

2.3.3. Digital Transformation in Integrated Value Chain

The potentials and impact of digital transformation in creating a more integrated value chain enabling increased efficiency of various firm functions reduce lead times, as well as enabling better control over business operations have been discussed. According to Bjorkdarhl (2020), with digital transformation sharing of information among systems and functions, such as production and enterprise resources planning becomes easier and contributes to improved coordination, visualization, and planning of important business processes. This is because manufacturing firms share data have many relationships and have to share information (a vital; element of production) across organizational boundaries with suppliers and customers. The use of machine algorithms and platforms has been discussed to be of relevance in adapting supplier interface into the organizational environment and limiting interaction to a single digital procurement channel (Bjorkdarhl, 2020). The novelty of this development has been explained in terms of enabling manufacturing enterprises and their suppliers to have improved collaborative control over materials and components and reduces inventories (Ardito et al., 2019). Even more so, experts have discussed these translate to a source of competitive advantage for manufacturing enterprises who also incorporated their customers’ interface into their production system control. Bjorkdarhl (2020) added that by transforming the value chain digitally, there is improved traceability throughout the enterprise’s value chain activities based on fast and accurate tracking of the position of a specific customer order in the supply chain using machine learning, or by linking the end products to data from the process operations. While the primary aim of digital

transformation has been linked to key objectives including efficient manufacturing process operations, development of superior products with cutting edge modalities as well as more integrated value chain performance all of which are integral in cutting or lowering total cost, experts have as well discussed digitalization to offer equal potentials or better chances to increase revenue than to lower costs (Bjorkdarhl, 2020; Ghobakhloo, 2020). In this context, digital transformation comes with the development of a new business model such as the complementary provision of products and services which maximized value for customers and contribute to the growth strategy of a manufacturing enterprise

2.4. Digital Paradigms in achieving Digitalized Manufacturing Process Operations

The market landscape is changing in terms of the increasing demand for high-quality customized products in variable batches that are timely delivered. This market development and the trend have created a new form of competition, forcing manufacturing business enterprises to adapt and improve their business processes by leveraging the use of flexible, efficient, and reconfigurable plant structures that needs new control and management systems that demonstrate efficiency, robustness, reality awareness in utilizing manufacturing resources (Trentesaux et al., 2016; Borangui et al., 2020). Quintanilla and colleagues explained this new initiative in manufacturing line operations as the organic interaction between the physical and informational worlds that are pronounced in the virtualization of reality-reflecting structural elements (products, orders, and resources) that are being managed in service oriented architectures (SOA) that are solely developed for the integration of technical and business layers of a manufacturing enterprise (Quintanilla et al., 2014).

Industrial experts have explained that industry 4.0 in manufacturing line operations entails the use of cyber cyber-physical production systems (CPPS) which facilitate digital representation, intelligent services, and interoperable interfaces in supporting flexible, agile and networked manufacturing environments (Borangui et al., 2020). Advanced technologies are at the heart of industrial 4.0 in a manufacturing environment as experts have discussed the 3I paradigms (intelligent manufacturing, intelligent interconnecting orders, and decision making) that are integral in achieving smart manufacturing in a digitalized process operation environment (see fig 2).

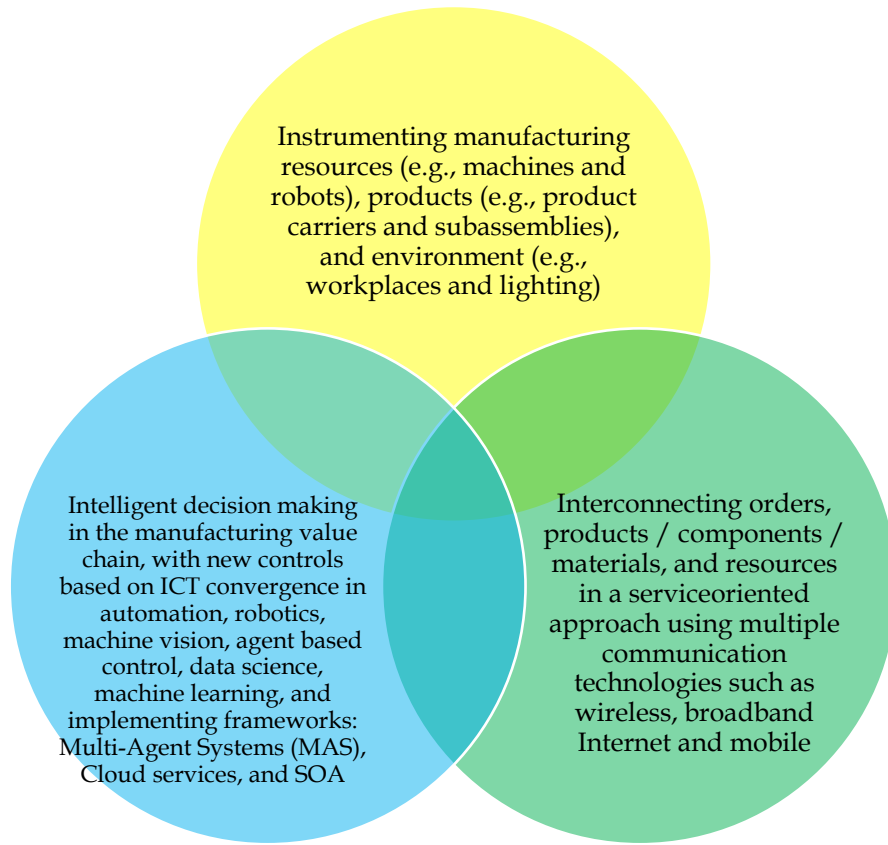


Figure 2: The 3I paradigm of Industrial 4.0

The organic synthesis of these three paradigms is what has been described in digitalized manufacturing process operations. While digital manufacturing is a concept that cannot be separated from the principle of industrial 4.0 which is not restricted to the digitalization of manufacturing processes alone, researchers and experts focusing on the specific role that advanced technologies can play in manufacturing processes has defined digital manufacturing as “the transformation of supply, production (with planning) and delivery operations of a networked company and uses intensively digital models (twins) and ontologies” (Borangui et al., 2020). Monostori et al (2016) also explained the digitalization of manufacturing processes as the virtual twin extension of an enterprise’s physical asset, process, product, that is persistent in a real-time environment and can be shared in a cloud database with other plant entities.

Researchers have described resource and process virtualization as the major components that are at the heart of digital manufacturing and which enables any enterprise to build a

competitive advantage and achieve optimum efficiency through intelligent decisions making with the use of machine learning and cloud services (Borangui et al., 2020). In this context, manufacturing enterprises are able to develop a competitive advantage with resource virtualization that assumes the creation of extended digital models of the three categories (products, materials/resources, and market orders) of physical entities that are specific for manufacturing using the digital twin technology (i.e. virtual extension of the physical assets). One of the advantages of resource and process virtualization, as enabled by digital manufacturing, has been explained in terms of the capacity of creating and managing virtual machines (VM), achieve a streamlined and balanced level of coordination of various shop floor activities with the use of computer-based control which fulfill the role of “intelligent beings” that mirror parts of the reality, and need to be deployed in industrial systems where they interact with planning, scheduling, and control entities in such way that no limitations relative to the corresponding reality, e.g., controlled processes, are introduced. In the same vein, it has also been explained that resource and process virtualization stimulates a product-centric approach, in which the product directly requests processing, assembling, and handling from available providers while it is in execution, delivery, and use stages (Trentesaux et al., 2013)

2.4.1. Digital Manufacturing Enablers

As digital manufacturing enables the development of a sustainable internet economy for industrial logistics - agile relative to markets and centered on customers, the key requirement of digital manufacturing is explained in terms of the use of advanced, integrated information, communication and control technologies (IC2T) with core technologies which serve the purpose of establishing a wide-ranging, Internet-scale platform for networked, intelligent production that effectively connect all the concerned stakeholders (technology providers, manufacturing plants, supply chains, and service providers) (Borangui, 2011). Initiatives including process virtualization are at the heart of digital manufacturing through which various shop floor activities can be seamlessly controlled and optimized, and industry 4.0 experts have described various systems, advanced tools, and embedded devices that can enable smart manufacturing operations and hence the development of competitive advantage in a manufacturing environment. The major enabler of digital manufacturing has been described in terms of cloud services developments (Monostori et al., 2016; Quintanilla et al., 2014; Borangui et al. 2020)

According to Kubler (2016), Cloud services development in manufacturing represents an evolution of networked and service-oriented manufacturing models that comprise a pool of shop floor reconfigurable and interchangeable items and may access a shared pool of computing devices according to cloud computing (CC) principles Kubler, 2016). It has been explained in the literature that cloud computing is not new to manufacturing enterprises as it has been adopted and continues to be used on the higher layers of business processes for supply, digital marketing, and Enterprise Resource Planning (ERP). However, the use of cloud computing in real-time production and logistics layers is still in the abstraction stage (Helo et al., 2014; Borangui et al, 2020). The role of cloud computing in digital manufacturing operation has been said to enable manufacturing enterprises to employ the use of tools like SaaS (Software as a Service)-based solutions to solve problems for globally optimizing the management of client orders, matching capacity and demand or increasing market share by client segmentation. The role of cloud computing services as an enabler of digital manufacturing has also been explained facilitating the use of 3D printing and shape modeling techniques in manufacturing operations.

Also, researchers have explained that cloud computing not only enables smart management of a networked company in the industry but also of high relevance in achieving smart manufacturing in the production layer of enterprises in which high production volumes and/or variable batch sizes and/or frequently changing product types are notable features. Thomas et al (2011) added that cloud computing enables intelligence manufacturing which is based on sustainability and resilience of production processes. In the same regard, researchers have as well explained that the market is demanding products that are highly personalized/customized, and integrating high-level SaaS cloud models with CMfg models at the production level allows for service-oriented product development and mass customization, in which customers can order, configure, select, and use customized resources and services, ranging from computer-aided engineering software tools to after-sales services (Wu et al., 2014).

In addition to enabling production to be shifted from product-oriented processes to a customer and service-focused processes, the other advantages of cloud manufacturing have been described in terms of enabling a novel platform through which organic synthesis of man, equipment, and materials can be achieved through the industrial internet of things (IIOT) as well as enabling a platform for analyzing big data and intelligent decision making for reality mirroring, robust, opportunistic and auto-configuring control. Specifically, the Internet of Things

or Industrial Internet of things (IIoTs) has been described as tools enabling pervasive presence of things (manufacturing assets and smart objects) in the business environment and facilitating improved communication— using various identification and tracking technologies such as wired and wireless sensors and actuated network, enhanced communication protocols, etc.—with one another in achieving common goals (Sisinni et al., 2018). Other advanced tools which enable and support digital manufacturing have been discussed in the literature. For instance, machine learning (ML), as well as deep learning (DL) algorithms, have been described as artificial intelligence development which supports digital manufacturing through the use of structure and function that mimic human learning to cascade and transform data through layers of processing. Other technologies including manufacturing execution systems have been described to be relevant in controlling the material flow on the shop floor while big data technologies come with the advantage of storing large amounts of data at high speeds in a real-time environment.

2.4.2. Pharma 4.0 and Digital Transformation

With the wide array of potentials conferred by industry 4.0, the concept of pharma 4.0 has become an industry-specific variant of digital transformation in the pharmaceutical industry environment. Pharma 4.0 is a concept pioneered by the ISPE group and relates to innovative development in the specific manufacturing environments of the pharmaceutical and biopharmaceutical industries. As the latest industrial development principle poised for adoption, experts have discussed pharma 4.0 as a new manufacturing operating model which requires full digital maturity as it will be accompanied by large investments the introduction of multiple new advanced technologies such as Cloud-based data management and advanced analytics which are the principal components enabling the full system integration of cross-functional activities generating a large amount of data that need to be analyzed and shared across the virtualized value chain. While the current pharmaceutical manufacturing system is transitioning from mass production to development and manufacture of personalized medicines to a smaller segment, digital technologies have been described to hold the key in addressing the issues of supply chain complexity (due to increasing global outsourcing in response to cost pressure) as well as quality risk issues due to lack of global oversight and less control over end-to-end processes in a less synchronized tradition cross-functional production system. According to Mazano and Langer (2018), pharma 4.0 represents a transforming approach to the current

pharmaceutical manufacturing system through the use of advanced technologies and tools, based on cloud-based systems, that contribute to improved process optimization, process excellence, and continuous improvement. While the pharma 4.0 initiative stem from industry 4.0, the concept promises enhanced opportunity in terms of product safety and security through digitalization, data analysis technology, Internet of Things (IoT), continuous manufacturing, and artificial intelligence technology (Kumari, 2020).

While experts have discussed that not all aspects of industrial 4.0 are adaptable to a Pharma 4.0 environment due to the tight regulations of the pharma environment, digital transformation will eliminate the use of nostalgic paper filing with the implementation of a virtual value chain that relies on seamless, real-time data exchange. Even more so in the aspect of data integrity tops the list of industrial regulators, digital transformation has a place in the pharma industry 4.0 environment in maintaining the integrity of the enormous amount of process data that are collected in a real-time environment (e.g. on-line process operations) which are to be stored and secured in a single cloud-based data management platform.

2.5. Appraisal of Potentials of Digital Transformation, and Tools in Pharma Environment

Industry 4.0 is has become a dominant concept of adoption across different industries and continues to gain increasing popularity. The pharmaceutical environment is one of the most sensitive and tightly regulated industries and pharma companies are always in the spotlight as their manufacturing operations is characterized and guided by an ethical dimension of the concept of quality (i.e. zero defects in the product) which is important in safeguarding the health of consumers (patient) throughout the lifecycle of the product in compliance with regulatory guidelines and stipulations (Minero and Augeri, 2018).

While the pharmaceutical industry is one of the most rigid industries when it comes to making changes, various elements of industry 4.0 have been poised for adoption in a pharmaceutical manufacturing environment. Industrial experts, researchers, and scholars alike have discussed the relevance and potentials of industry 4.0 and its element in the pharma environment. According to Ehrhardt and Behner (2016), digitization holds tremendous potential in helping companies adapt as the digital transformation of processes by pharmaceutical firms

can assist in rising to the challenge of increasingly competitive price (and therefore cost) pressures by being more efficient operations in their operations.

Vaidya (2018) discussed the relevance of digitalization in pharma 4.0 context as the application of industrial 4.0 concepts including cyber-physical systems (CPS), the internet of things (IoT), industrial internet of things (IIOT), cloud computing, cognitive computing, and artificial intelligence to optimize all aspects of the manufacturing process and throughout the entire product life cycle (Vaidya, 2018). The implementation of these adaptive and innovative technologies from the Industry 4.0 revolution in a pharma environment comes with the potential to develop and establish more robust and agile production processes defined by fewer interruptions and defects, with higher quality management levels for pharmaceutical companies (Aksu and Yegen (2021).

According to Gaertner (2015), digital transformation holds the key for pharma in the face of the challenges and changes in the pharmaceutical industrial landscape caused by the increasing and changing customer demand for personalized medical supplies, institutional pressures to cut down the price of drugs as well as an increasing bottleneck in operation due to various unanticipated disruptions and increasing business activities. Even with increasing customer demand for personalized medical products and the need to achieve speed to market, experts have discussed the greater possibility for pharma and biopharma organizations to upgrade their pharmaceutical production plant to a “reconfigurable factory” which comes with the potential to achieve mass customization of personalized drugs for different demands by Industry 4.0 elements integration (Manzano, and Langer, 2018; Minero and Augeri, 2018)

Pharmaceutical industry experts have also discussed the various roles that advanced technologies can play in achieving continuous improvement in a manufacturing environment that is based on the concept of pharma 4.0. The role that technologies including big data and artificial intelligence can achieve in the pharma 4.0 manufacturing environment has been explained in terms of enabling enhanced production planning based on inferences drawn from predictive analysis with the large volume of available data sets. Manzano and Langer (2018) maintained that as much as 70% of all manufacturing data collected in pharmaceutical production processes are not used and that pharmaceutical manufacturing data captured in operations most times usually result to waste. This is because, in the areas of product development and

manufacturing operations, the use of varied single traditional systems represents the standard approach through which GxP data are collected and managed. The researchers explained that with product manufacturers facing increasing pressure to optimize manufacturing operations, the underutilization of production data remains a challenge. In achieving manufacturing performance, the relevance and importance of existing data that has been captured to be of potential use in gaining insights about processes and operations. The industrial 4.0 (hence pharma 4.0) paradigm has been described to be of significant potential to address the use of manufacturing process data collection and underutilization through the use of real-time big-data-driven platforms and tools as well as developments including the industrial internet of things (IIoT) (Manzano and Langer, 2018). Reinhardt et al (2021) added that effective knowledge web across company boundaries and big data analytics can improve process monitoring performance and achieve sustainability by reducing material waste, overproduction, and energy consumption (Reinhardt et al., 2021).

Advanced technologies have been earmarked for significant adoption in the pharma environment which is becoming information-intensive due to the level of interaction between companies, consumers, and regulatory authorities. The potentials of industrial 4.0 technologies and tools like the industrial internet of things in the pharma manufacturing operations have as well been explained in terms of enabling lower operational costs and shorter time in automation with the use of collaborative information technology, which offer new opportunities for reliable and secure support to actions and decisions throughout the operations (Minero and Augeri, 2018). In the areas of shifting from a product-focused model to a patient-focused business model, experts have discussed that pharma operation is shifting from mere focus on products to increased focus on patients and in a world where the integration between information and product can bring to increase the therapeutic adherence digital technologies (like IIoT) are said to hold the key when creating personalized drugs and services (e.g. wearable devices). The potentials of these technologies in the level of interaction with regulatory authorities have been described in terms of shortening of the information distance, which creates new scenarios such as Quality Metrics and risk-based inspections (Minero and Augeri, 2018).

2.5.1. Literature Gap

The concept of digital transformation has been well discussed by experts and has gained significant interest among researchers. While industry 4.0 digital technologies are finding relevant application in the other manufacturing sectors, the pharmaceutical industry is still behind in the adoption of some of these technologies despite the popularized concept of pharma 4.0. In the series of works of literature consulted, two major gaps were identified

1. The potentials of digital transformation and some of its tools in the manufacturing environment has been majorly discussed from the perspectives of their application in other industrial settings and while it cannot be said that no knowledge exists on the role of digital transformation in pharmaceutical industry-specific environment, it is rather limited especially in the area of manufacturing operations as no major research literature have explored this in the way that the role of digital transformation and digital technologies has been addressed in the aspect of product innovation (as studied by Landwehr, 2015) as well as pharmaceutical product marketing (as studied by Olubunmi and Colleagues, 2015). This is the first gap intended to be bridged
2. Presently, there is no research knowledge on the digital maturity of the Nigerian pharma industry or on the possible or use of digital technologies in manufacturing operations. Hence another gap identified and intended to bridge in the literature is to account for the potentials of digital manufacturing and its enabling tool in the Nigerian pharmaceutical manufacturing environment.

2.6.2. Conceptual Model

According to Bjorkdarhl (2020), the effect of digital transformation in the manufacturing environment are majorly pronounced in three major areas including

1. Efficient product development,
2. Efficient manufacturing, and
3. Efficient services in well-integrated and coordinated value chains.

Based on these three concepts, the following conceptual model is developed in order to achieve

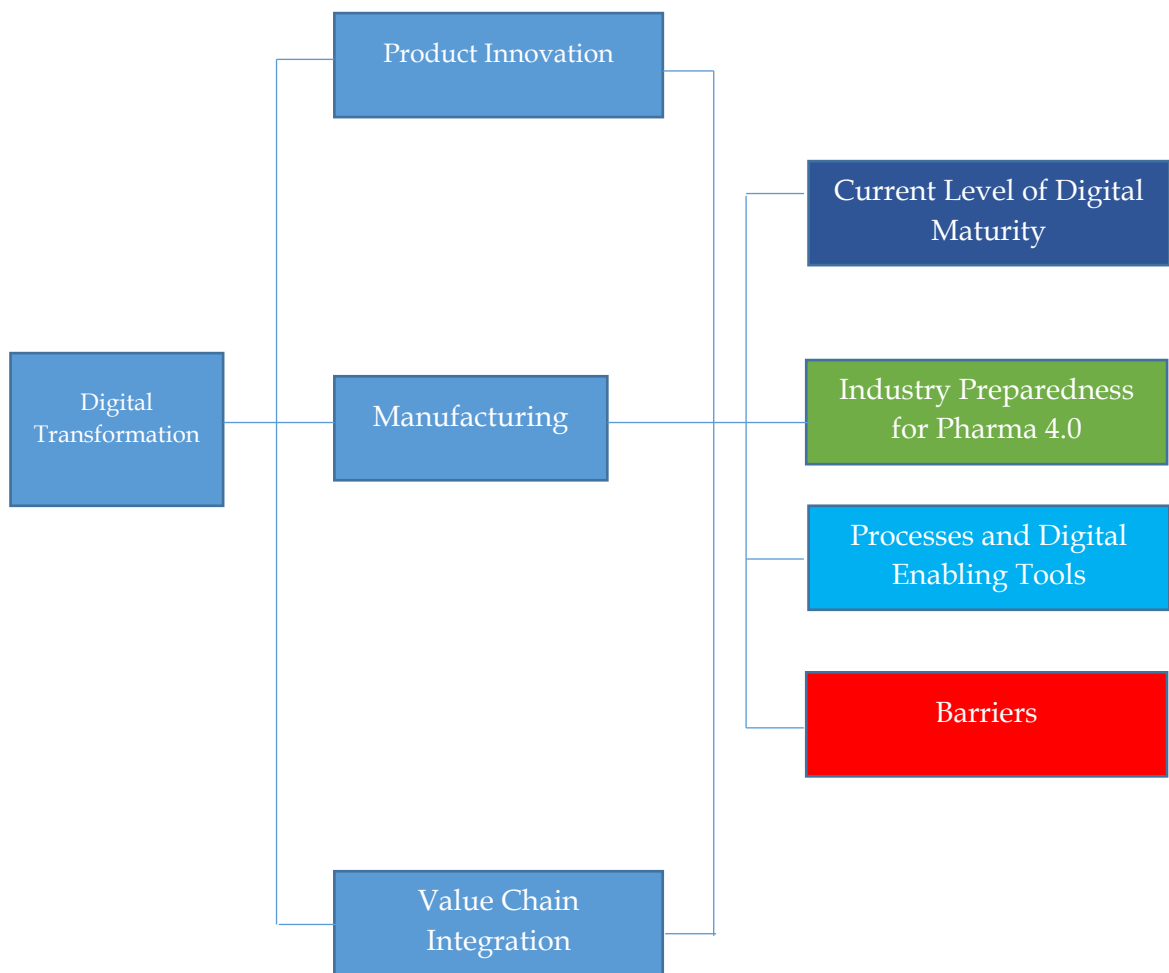


Figure 3: Conceptual Model

Using this conceptual model, this research specifically focused on the potentials of digital manufacturing in the Nigerian pharmaceutical industry environment. In achieving a robust understanding of the relevance of digital transformation in the manufacturing operations, the

research studies for major factors including the current level of digital maturity in the industry; the preparedness of the industry for the concept of pharma 4.0, and adoption of industry 4.0 elements; the potential manufacturing areas in which digital transformation enabling tools can be achieved; and lastly the potential barriers to effective digital transformation in the Nigerian pharmaceutical industry.

2.6. Chapter Conclusion

In this chapter, a holistic review of the literature was carried. The research gap is identified and stated to be bridged and the conceptual framework for the study is built in accordance with the stated objectives of the study.

CHAPTER THREE: METHODOLOGY

3.1. Research Overview and Study Design

The pharmaceutical industry environment is changing and with the increasing price and cost pressure, and market demand for personalized, digital transformation in the pharma environment has been earmarked as a way through which pharma companies can be more efficient in their pharmaceutical manufacturing operations. While the pharmaceutical industry operates in a tightly regulated environment and unsurprisingly one of the most rigid industries which hardly make changes to the way manufacturing processes are being carried out, the recent pace change across other industries in the digital age is pushing pharma companies to the adoption of advanced digital technologies in improving process operations as well as in fostering competitive advantage. It is on this premise that this research is conceived to study the relevant role that digital transformation and enabling tools can play in the manufacturing process operations for companies operating in the Nigerian pharmaceutical industry.

To achieve this aim, and given the dearth of knowledge existing on the application of digital technologies in manufacturing operations in the Nigerian pharmaceutical industry, an exploratory research design is adopted for this study. An exploratory research design usually proves to be valuable in gaining new insights on a concept which little or no knowledge exists and set out to establish new knowledge by asking a broad range of questions from experts who are conversant with the research concept being studied as well as the industry is explored. Thus, the idea in this study is to gain insight into the digital maturity in the Nigerian pharmaceutical industry and how the application of digital technologies in product manufacturing can contribute to excellent manufacturing operations for pharma companies (secondary pharmaceutical companies) whose major competitive advantage is based on speed to market and competitive product pricing, the exploratory research design chosen is in line with the focus of this study.

3.2. Research Onion Framework

To effectively achieve the aim and smart objectives of the study, this research adopts other research method concepts that are described by Saunders et al (2009) in their developed research onion framework (see fig. 4). These concepts cover the adopted philosophy; the research strategy being employed; the time horizon and chosen methodology; the data collection approach; as well as the choice of the data analysis method being used in unraveling key findings from the data collected within the scope of the study. As applicable in the present study, all these concepts are discussed under various sectional headings

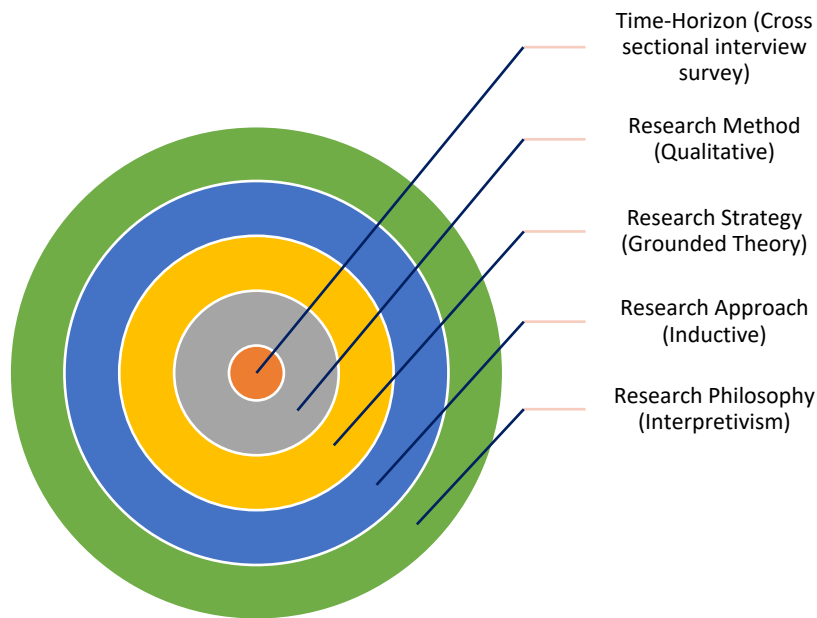


Figure 4: Research Onion Framework

3.2. Research Philosophy

According to Saunders et al (2009), a research philosophy captures the important assumption about the view of a researcher about a concept to be studied. These assumptions are what underpin the research strategy and method to be used. Interpretivism also enables the human element to be included in a study design that cannot be independently carried out through mere observations and measurements. For this study which requires expert opinions in achieving a robust understanding of the role that digital transformation can achieve in pharmaceutical manufacturing process operations, the interpretivism philosophy is adopted in making provision for human elements who will be part of the study to share a wide range of opinions and anecdotes on the digital maturity of pharma companies in the Nigerian pharmaceutical industries and the

various aspect of pharma manufacturing operations which can be digitally transformed in achieving excellent manufacturing operations. The use of this research philosophy within the scope of this study will prove to be integral in

- Facilitating a way through which the participants can be engaged in an in-depth interview with the use of semi-structured questions that are developed through the inductive reasoning of the researcher.
- Enables the researcher to be part of the study as respondents will be engaged through interactive open-ended sessions leading to the collection of data that are rich in subjective and objective opinions of all experts in the Nigerian pharmaceutical industry.

3.3. Research Approach

An inductive research approach is as well adopted for this study. In their book “Research Methods for Business Students”, Saunders et al explain that research will always involve the use of an approach that should be selected in accordance with the chosen research philosophy (Saunders et al., 2009, p.124). Thus, the inductive research approach which enables a researcher to collect data and develop theory from the analysis carried out is chosen for this study. The rationale behind the selection of this research approach is based on the interpretivism research philosophy chosen for this study on one hand. On the other hand, the broad range of opinions that the Nigerian pharmaceutical industry experts acting as the respondents in this study are expected to be grounded in themes that can be used to formulate theories in explaining the level of digital maturity in the Nigerian pharmaceutical industry as well as the novel role that digital transformation and enabling tools can play in achieving excellent pharmaceutical manufacturing operations such as in the areas of shop floor activities, product packaging, quality testing amongst others

Also with the existence of a dearth of research on the role of digital transformation in manufacturing operations in the Nigeria pharmaceutical industry, the inductive research approach chosen for this study will enable sound theory formulated to be subjected to hypothesis (not within the scope of this study) which can be tested.

3.4. Research Strategy

A grounded theory research strategy is chosen for this study as it comes with the advantage of constructing theories from the quality-rich data that are being collected from respondents. The selection of this research strategy is also to enable the development of research interview questions based on inductive reasoning and as well in accordance with the interpretivism research philosophy and inductive research approach chosen for this study (Saunders et al., 2009)

3.5. Research Method

Qualitative data that are highly rich in the experts' subjective and objective opinions as well as their resourcefulness of the new wave of the industrial revolution caused by the application of digital technologies in manufacturing processes are being used in this study. In collecting this data type, a mono method qualitative research method leveraging the use of semi-structured interviews is chosen for the study. As all experts are sourced from different pharmaceutical companies in the Nigerian pharmaceutical industry to be engaged through separate interviews, their response patterns are anticipated to contain similar themes that will be used to construct theories to be used in discussing various research findings to be made.

3.6. Time Horizon

This study is cross-sectional in nature and conducted using a survey approach through which experts from leading pharmaceutical industries are enlisted and engaged through series of interview questions within a realistic time frame.

3.7. Collection of Primary Data

To achieve the goal of studying the role of digital transformation in the manufacturing process, the research relies on the strong use of primary qualitative data.

3.7.1. Sources

a. Study Population and Research Instrument development

This study's population is composed of pharmaceutical company leaders, managers, and experts in the Nigerian pharmaceutical industry. These groups of individuals are identified as

ideal respondents that are enlisted and engaged with series of questions which enable them to share anecdotes about how pharmaceutical companies in the Nigerian pharmaceutical industry improving their manufacturing processes and are advancing towards the new industrial norm calling for the application of digital technologies in pharma product manufacturing.

In order to achieve this, a semi-structured interviews strategy is employed. This type of interview strategy combines both the use of structured and unstructured questions which enables interviewees to freely explain their quality-rich subjective and objective opinions based on a diverse range of questions being asked. In line with the semi-structured interviews to be conducted, open-ended questions will be used in engaging the respondents. The questions are dichotomous and non-dichotomous in nature and are developed in such a way that respondents are able to give in-depth insights on the concepts being discussed in the interactive session. Therefore, a self-developed sixteen (16) item questions henceforth called the research instrument will be used to engage each of the respondents sampled from the Nigerian pharmaceutical industry environment. (See Table 2).

Table 2: Research Interview Questions

Interview Questions	Research Objective aimed at
1. The need for business organizations to digitize and transform their business processes has become the major topic of discussion, what is your opinion about this development? 2. Could you share your opinion on what digital transformation means in the pharma environment? 3. Are there any areas of pharmaceutical operations that your organization has applied digital technologies or considering the use of digital technologies? 4. It is popular to see Nigerian pharma companies using digital channels for their marketing operations, could you please give a general assessment of the level of the use and application of digital technologies in the area of manufacturing operations?	To study the current level of digital maturity in the Nigerian pharmaceutical industry environment
5. What would you say about the Nigerian pharmaceutical industry's inclination towards the new norm of industrial 4.0 which we all know as the era of smart manufacturing operation? 6. The concept of industrial 4.0 has influenced the now popularized pharma 4.0 which entails computerization of manufacturing	To assess the Nigerian pharmaceutical industry preparedness for the new pace of change that has to do with the adoption of

<p>processes in the business model, what would you say about your organization's development around this?</p> <p>7. The traditional ways of developing and manufacturing products are becoming obsolete, how well is your organization/ industry is preparing for the new change?</p>	<p>digital technologies in manufacturing operations</p>
<p>8. Digital technologies have a wide range of applications in different areas. In the aspect of product development and product quality testing, could you describe any relevant role that digital technologies can play in Nigerian pharma companies' environment?</p> <p>9. Technologies like the manufacturing execution system (MES) have found significant use and application in other industries in overseeing production activities, what would you say about the use of this in the Nigerian pharma environment?</p> <p>10. With the increasing amount of data being generated in various aspects of pharma manufacturing operations, could you share your opinion of the role that technologies like big data analytics can play in the pharma environment?</p> <p>11. Could you share your opinion on how Nigerian pharmaceutical would benefit from the application of digital technologies like the Internet of Things (IoT), augmented reality, computerized maintenance management system (CMMS) in maintaining manufacturing equipment effectiveness?</p>	<p>To explore the key areas of manufacturing processes in which digital technologies can be of relevant adoption and how the application of digital technologies can translate to operational excellence</p>
<p>12. Digital transformation is still gaining ground in the Nigeria pharma environment, what would you say about this initiative for pharma companies when developing their business and corporate strategies?</p> <p>13. Specifically, price and speed are market drivers which influence the business model of Nigerian pharmaceutical companies, what potential impact do you see the digital transformation to have on pharmaceutical companies' business model in Nigeria?</p> <p>14. Which aspect of pharma operation and processes would you recommend that Nigeria pharma companies should invest in in order to be more effective and competitive?</p>	<p>To Study the potential impact of Digital transformation on Nigerian pharma companies' business model and strategies</p>
<p>15. Could you please share your view on any specific or general industry barrier(s) and challenges that you see facing pharma companies in the Nigerian pharmaceutical industry when fully adopting digital technologies such as smart sensors, artificial intelligence, cloud computing, etc. the manufacturing line?</p>	<p>To assess the specific barriers to the adoption of digital technologies in the manufacturing process in the Nigerian pharmaceutical industry</p>

16. Could you suggest some of the ways through digital transformation in manufacturing operations can be successfully achieved by pharma companies in the Nigerian pharmaceutical industry?

To suggest ways through which pharmaceutical companies can best position themselves for digital transformation and overcome potential barriers in adopting digital technologies in manufacturing operations.

b. Interviewee Selection and Data Collection Process

In enlisting respondents for the study, a non-probability sampling method and purposive snowballing sampling technique were used. The purposive sampling strategy enabled specific respondents to be recruited based on convenience and how they fit into the study plan. The snowballing sampling technique being used is integral in enlisting the help of respondents to recruit another similar respondent for the study. This enabled a “web of respondents” having similar characteristics to be engaged with the same set of questions with the idea that their response pattern will show repetitive themes that can be identified through thematic analysis and hence used to form theories in explaining the findings made. With the use of these sampling techniques, ten (10) to fifteen (15) respondents are to be sourced from different pharmaceutical companies in the Nigerian environment.

Based on the agreed schedule with the respondents, the series of interviews will be conducted either with the use of mobile phone calls or zoom applications depending on the one which is the most convenient for respondents. The interviews will last for a maximum duration of 30 minutes. Audiotaping and note-taking will be used as the choice of the data collection method.

3.7.2. Access and Ethical Issues

To successfully conduct the research, various ethical issues that have to do with primary research access, participant consent, and confidentiality as well as overall credibility of the research would be addressed. These are discussed in details

Research Primary Access

The research will be conducted in the Nigerian pharmaceutical industry setting and respondents to be engaged will be sourced from leading pharmaceutical companies in the country. To eliminate any bottleneck in enlisting respondents or scheduling the interview, an

awareness is intended to be created about the purpose of the study. This will be achieved by drafting a research letter paper that details the scope of the study in terms of its broad overview and the goals to be achieved. The letter would be sent to respondents across the selected pharmaceutical companies in the country. In so doing, an understanding of the study's general intention would be achieved with potential respondents who could take part in the study.

Informed Consent and Participants' Confidentiality

Respondents who are successfully enlisted for the study would be informed about the objective of the study. The demand requirements of the study would as well be duly communicated to all respondents. This would be achieved by drafting an "Informed Consent Form" containing all necessary details and providing the respondents with such a document. Respondents would be given the luxury to withdraw at any stage of the research. Also, the identity of respondents would be kept anonymous and only the information which respondents permitted would be used when reporting the findings

3.8. Approach to Data Collection

A qualitative data analysis method will be carried out. The interview responses would be analyzed to unravel the key findings that enable the research questions to be answered and achieve the stated aim and objectives. In this regard, Thematic content analysis based on the use of six guiding principles that are outlined below would be used

- **Transcribed text reading:** All audiotaped responses collected from the interviews will be transcribed into text equivalents and updated with the note taken during each of the separate interviews. Reading and re-reading of all transcribed texts will be carried out so as to become familiarize with the data and identify similarities in the response pattern of respondents
- **Coding based on similar response pattern:** The transcribed text will be organized in a meaningful and systematic way through text coding which is used to identify the salient points in the response pattern on one hand and as well answer the research questions on the other hand
- **Generation of a theme:** The identified code will be combined together to identify preliminary key themes which ultimately some of the research questions as well as bring into light the findings made within the scope of the study

- **Review of the themes:** The identified preliminary themes will be reviewed, and modified to answer specific research questions and identify additional findings
- **Renaming of the reviewed themes:** All identified and reviewed themes will be renamed into theories that can be discussed
- **Writing up the theme:** This will be done to concisely capture and discuss research findings that are unraveled in the analyzed responses. Also, respondents' opinions would be quoted and used whenever appropriate to support the various themes which will be discussed as major research finding within the scope of the study

Maguire and Delahunt (2017)

3.9. Chapter Conclusion

In this chapter, the research onion framework by Saunders et al (2009) was employed to develop the research method being used in engaging respondents and collecting data on the role that digital transformation can play in enabling improved and excellent manufacturing processes in the Nigerian pharmaceutical industry environment.

CHAPTER FOUR: RESULT ANALYSIS

In this chapter, the various findings that were made within the scope of the research are established and discussed.

4.1. Interview Process Summary

In this present study, 10 respondents were enlisted for the study, and five interviews were successfully conducted. All respondents that were enlisted and successfully engaged in separate in-depth interviews are experts from different pharmaceutical companies in the Nigerian pharmaceutical industry. The maximum duration of an interview was 30 minutes in which sixteen (16) separate questions were asked from each of the participants in the study. In Table 1 below is a summary of the profile and characteristics of the respondents engaged in the interviews

Table 3: Respondents Characteristics

Interviewee	Gender	Role	Experience
Respondent 1	Male	Operation Manager	15 years
Respondent 2	Female	R&D Lead Scientist	13 years
Respondent 3	Male	Quality Assurance Manager	10 years
Respondent 4	Female	Pharmaceutical Technologist	10 years
Respondent 5	Male	Validation Manager	12 years

4.2. Thematic Content Analysis Result

The audiotaped responses collected from each of the separate interviews carried out were transcribed into text and thematic data analysis carried enabled the identification of key themes which reflect the potentials of digital transformation in the Nigerian pharmaceutical industry environment. The six key themes identified in the pattern of responses of all respondents over the sixteen interview questions that were asked are as follows

1. Industry Awareness of Digital Transformation— from Rigidity to Flexibility
2. The Popular use of Paper and Basic IT Tools— Digital Immaturity in the Nigerian Pharma Environment
3. Digital Mindset Cultivation and Investment in IT Infrastructures—The Nigerian Pharma Industry Preparedness Approach to Industry 4.0 and Pharma 4.0
4. Reduced Waste, improved quality with PAT tools, and Increased Productivity with Data— Digital Tools Potentials in Nigerian Pharma
5. Cost-Efficiency, Improved Product Quality, and Speed to Market

6. Knowledge Gap, Lack of Funds and Poor Infrastructures—Barriers in Digital Transformation

4.3. Research Findings

In the discussion of six identified themes, responses and opinions of the experts engaged in the interviews were quoted are used in supporting the discussion. Each of the respondents that were quoted is referred to by their professional role and the years of experience given. For instance, male respondent 1 who has been working as an operation manager for 15 years in a leading pharmaceutical company in Nigeria is simply represented as “**Operation Manager with 15 years of Experience**”. All other respondents are also identified and represented by their role and years of experience given in the interactive discussion (See Table 1). The findings made are discussed under the various subheadings

4.3.1. Industry Awareness about Digital Transformation— From Rigidity to Flexibility

In the series of separate interviews carried out, the respondents were asked series of questions in order to access the current level of digital maturity of the Nigerian pharmaceutical industry. In achieving this, the knowledge and understanding of all respondents on the concept of digital transformation in the industrial environment was first discerned as respondents were separately asked to discuss what it means for manufacturing enterprises to digitally transform their processes (**Interview Question 1**). All of the respondents demonstrated an in-depth understanding of the concept of digital transformation in an industrial environment as the need to achieve efficient and improved operation, develop superior business strategy, tap into new resources, and achieving excellent business operations were among the key elements identified in the pattern of responses.

Some of the quoted responses reflecting this finding are as follows

Quality Assurance Manager with 10 years of Experience: “We all know that the industry landscape is changing and digital transformation which captures the adoption and use of digital technologies in existing business process and tapping into new opportunities has become a new norm”.

Validation Manager with 12 years of Experience: “The world is evolving and I believe that digitalization has become the next big thing in moving in the right direction when it comes to improving business process”.

R&D Scientist with 13 years of Experience: “The world is obviously moving towards digital era and I believe they need to transform business and take some processes into a virtual environment has become an important strategy”.

Operation Manager with 15 years of Experience: “My take on the concept of digital transformation is that it is a unique development in its entirety and can be considered a disruptive innovation when we consider how all and sundry are embracing the initiative just to achieve improved business operation and getting the optimum output in the use of organizational resources”.

Pharmaceutical Technologist with 10 years of Experience: “I believe digital transformation is an important development in the industrial environment as it comes with the advantage of carrying out certain processes at reduced cost and improved productivity”.

In the same regard, all the respondents demonstrated awareness and understanding of digital transformation and as well showed a great level of understanding and resourcefulness on how digital transformation relates to the pharmaceutical environment when they were asked to share their opinion on digital transformation in a pharma environment (**Interview Question 2**). It is found out from the diverse range of opinions given by some of the experts in the interviews that digital transformation in a pharma environment represents a new way of doing things while transcending from rigidity to flexibility without negatively disrupting the expected performance outcome but rather achieving operational excellence.

Some of the expert opinions reflecting this finding are quoted accordingly as follows

Quality Assurance Manager with 10 years of Experience: “Digital transformation in a pharma environment means making changing changes to some or all of the processes to the advanced ones as much as they can be transformed without affecting the expected outcomes”.

Operation Manager with 15 years of Experience: “What I will say about digital transformation in a pharma environment is that it is a move away from rigidity to flexibility when you consider how traditional processes can be improved by going into virtual cyber-physical space”.

Validation Manager with 12 years of Experience: “In a pharma environment, it (digital transformation) represents a new way of carrying business activities by adapting digital; concepts and initiatives to new and current culture so as to improve business excellence”.

4.3.2. The Popular use of Paper and Basic IT Tools—Digital Immaturity in the Nigerian Pharma Environment

Digital maturity is defined in this study as the level at which advanced technologies are being used in different capacities and areas, with a digitally matured industry being one that is making the best use of digital technology and its associated culture and networks in every operation (Deloitte Development, 2017; Mugge et al., 2021). A digitally immature organization or industry on the other hand is defined in this study as one whose processes and operations are still based on the conventional approach in this current age in which automation, as well as the use of improved technologies, have become dominant features in the industrial landscape.

Since digital maturity is based on the actual and real-time use of advanced technologies in almost every aspect of manufacturing operations in an industry, the respondents were specifically quizzed on the use or consideration of the use and application of digital technologies in some or all of the pharmaceutical operations in their respective organizational setting and the Nigerian pharmaceutical industry at large (**Interview Question 3**). It was found out that pharma operations in the Nigerian industry are still based on the traditional manufacturing approach as the respondents, in each of the separate interviews carried out, discussed that pharmaceutical manufacturing processes in Nigeria are nowhere the level seen in the advanced world (who boast superior infrastructural and technological capabilities) and in the areas of product marketing is where major development can be pointed as most organizations relies on the use of IT tools to improve marketing operations but not drive production processes.

Quoted responses of the experts are as follows

Quality Assurance Manager with 10 years of Experience: “Most of our processes follow a traditional route which is mostly offline and where you will see something close to digital technologies is in the quality control and product testing area and in the area of shop floor activities, I can’t really point to any major technology and I can say that is the case everywhere for Nigerian pharma”.

R&D Scientist with 13 years of Experience: “We really don’t use digital technologies for manufacturing processes here and have not explored the opportunities of digital technologies in pharma in the Nigerian pharmaceutical manufacturing sector”

Validation Manager with 12 years of Experience: “Our organization has not imbibed the concept of 4.0 but we are considering digital transformation in the supply chain”

The experts were nevertheless asked to specifically give a general assessment of the use of digital technologies in various pharmaceutical manufacturing processes in the Nigerian environment (**Interview Question 4**). It was found out that the Nigerian pharmaceutical industry is still evolving and cannot be said to be digitally mature at present as some of the respondents explained the slowed pace of development in an industry that is still trying to adapt to change. In this regard, it was discerned that pharmaceutical manufacturing processes in the Nigerian environment follow a traditional approach such as relaying information to the production line with the use of papers for batch processing still the norm in almost every pharma company in Nigeria and the use of digital technologies is still in the consideration stage. Hence a convenient assertion made with this series of findings is that the Nigerian pharmaceutical industry is digitally immature

Some of the quoted responses are as follows

R&D Scientist with 13 years of Experience:” To be honest. I don’t think we are digitally mature because the Nigerian pharmaceutical industry is a bit way back and still evolving and adapting to change. If I am to say the level of use of digital technologies on a scale of 1 to 10, I will say 3”.

Operation Manager with 15 years of Experience: “To some extent, we have tried to keep up with the pace of the game of digital transformation by using some IT-driven system to optimize product marketing since we are entirely a secondary drug producing company but when it comes to how these drugs are being developed or manufactured, the truth is most pharma companies in Nigeria still follow the old approach and the sight of papers in relaying information to the product line for batch manufacturing is the norm”

Quality Assurance Manager with 10 years of Experience: “I can say where you will see the application of something like digital tools in the product sales and marketing and which are more of IT tools. So my take is that we are digitally immature presently”.

4.3.3. Digital Mindset and Investment in IT Infrastructures—The Nigerian Pharma Industry Preparedness Approach to Industry 4.0 and Pharma 4.0

The industry 4.0 concept has geared various manufacturing enterprises to be shifting their attention to what experts have discussed as smart manufacturing, advanced manufacturing, or digital manufacturing in a cyber-physical environment (Gaertner, 2015; Bjorkdarhl, 2020). The Nigerian experts engaged in the interviews were asked to discuss the inclination of the Nigerian pharmaceutical industry towards this initiative (**Interview Question 5**). It was found out that there is a positive inclination towards this latest industrial development as the respondents maintained that pharmaceutical organizations are investing more in improved IT technologies and systems while studying how the new industrial development progress.

Some of the quoted responses from some of the experts are as follows

Quality Assurance Manager with 10 years of Experience: “The Industry is moving towards that as people are becoming more aware of the need to be operationally more efficient in an economy in which information has become a new form of production resources and given the enormous amount of data our processes generate, we are now investing in IT technologies and platforms that can assist in mining these resources”.

Operation Manager with 15 years of Experience: “Even though it is occurring at a slow pace, I say our direction towards industry 4.0 which we call smart manufacturing can be appreciated because you can see pharma companies investing in ICT technologies which I think will give us more exposure on how cyber manufacturing can be adopted effectively with more knowledge and resources”.

Pharmaceutical Technologist with 10 years of Experience: “With industry 4.0 concept adoption, Nigerian pharma companies have the potential to go into smart manufacturing which I will describe as an efficient, productive and excellent approach to product development and product manufacture”.

Validation Manager with 12 years of Experience: “Industry 4.0 and pharma 4.0 are widely talked about in the pharmaceutical environment at the moment and while some companies are trying to implement the operating model others are still studying the development”.

With pharma 4.0 being a pharmaceutical industry-specific form of digital transformation and poised as an important business model for pharmaceutical companies around the world to adopt (Gaertner 2015; Aksu and Yeğen, 2021), each of the respondents were separately asked to discuss the developments in their respective organization around the pharma 4.0 operating model (**Interview Question 6**). From the series of opinions and anecdotes shared by respondents, it was found out that there is a level of preparedness in the various organizations of each of the respondents. Digital mindset cultivation which is based on an embracing understanding of the need to achieve digital transformation in pharma 4.0 context as well significant investment and restructuring in the areas of information systems in the pharma environment were discerned to be the strategic approaches towards pharma 4.0 in the organizational environment of the respondents engaged. Some of the quoted opinions and responses are as follows:

Quality Assurance Manager with 10 years of Experience: “Like most of the pharma companies in Nigeria, we are a secondary drug producing company and various strategic decisions are being made at the top level in my organization as we are preparing for the change. For instance, we have been considering the possibility of going paperless for some time now”

Validation Manager with 12 years of Experience: “our organization has not imbibed the concept of 4.0 yet, we are still in the consideration stage and studying how this new development will shape the industry future so that we won’t be left behind”.

Operation Manager with 15 years of Experience: “The first step we have taken is to ensure that the digital mindset and culture is imbibed by everyone as we believe industrial 4.0 and pharma 4.0 can only be achieved with workforce 4.0 and our effort are taking everyone in that direction and then see where can target immediately”.

Pharmaceutical Technologist with 10 years of Experience: “In the case of my own organization, the first step we have taken is to invest and restructure some of our IT platforms”.

R&D Scientist with 13 years of Experience: “The presence of some international pharma companies is pushing us top the digital world and our preparation towards pharma 4.0 has been great so far as we are now considering the prospect and feasibility of cloud manufacturing in our environment”.

4.3.4. Reduced Waste, improved quality with PAT tools/, and Increased Productivity with Data— Digital Tools Potentials in Nigerian Pharma

With the wide advantages of digital transformation in the aspect of product development and product manufacturing environment being discussed by various industry 4.0 critiques, researchers, and scholars alike (Manzano and Langer, 2018; Minero and Augeri, 2018), each of the respondents was asked to share an opinion on what role specific digital technologies would play in product development and product quality testing in the Nigerian pharmaceutical manufacturing environment (**Interview Question 7**).

The respondents demonstrated awareness and resourcefulness about the latest industrial development in the global pharmaceutical environment as they discussed the relevance and potentials of advanced technologies in achieving improved product quality development and testing in the Nigerian pharma environment. Some of the quoted responses are as follows

Pharmaceutical Technologist with 10 years of Experience: “Quality check is really important in pharma product development and manufacturing and I believe digital technologies will come handy as we can always do that in ongoing operations without any significant break in process”.

R&D Scientist with 13 years of Experience: “Of course, it (digital technology) will possibly increase the turnout of production because the manufacturing process is a long one which can be slow but with the introduction of digital technology, products can be developed, manufactured and tested seamlessly in a way that will enable them to come out”.

Validation Manager with 12 years of Experience: “Digital technologies in pharma manufacturing in the aspect of product development and product quality testing can come with endless advantages such as limiting batch defect and error rate, increased productivity which is what contributes to operational excellence”

The highly resourceful Quality Assurance as well as the Operation manager engaged in the series of separate interviews conducted discussed the role of specific technologies including 3-D printing and PAT tools which are usually used in pharmaceutical production line operations in achieving optimum product quality. The responses were quoted as follows

Quality Assurance Manager with 10 years of Experience: “Digital technologies like 3-D printing will be of novel impact in product development because with this technology you can always achieve product simulation and in the areas of product quality testing, PAT tools like chemometrics and all will be of novel application and in that way, it will assist in reducing batch defect which is one of the major challenges in pharma manufacturing here”.

Operation Manager with 15 years of Experience: “What I will say is that while pharmaceuticals cannot adopt all I4.0 tools, there are some specific ones like the PAT tools, chemometrics, process analyzers which will contribute to improved product manufacture and testing in the Nigerian pharma environment”.

All the respondents were also quizzed to share their opinion on the relevance and use of manufacturing execution system (MES) can play in overseeing shop floor activities in the pharma

manufacturing environment (**Interview Question 8**). The respondents also demonstrated an understanding of the manufacturing execution system and relate its relevance to having control on the issue of uncontrolled overproduction resulting from lack of visibility from ongoing manufacturing operations and hence amounting to waste

Validation Manager with 12 years of Experience: “MES use in pharma production activities in the Nigerian environment will be good innovation as it will be possible to reduce waste, reduce downtime and reduce cost”

Operation Manager with 15 years of Experience: “I’ve had experience with something close to MES system in the past and if I may say, it will be of significant relevance in Nigerian pharma environment because we can always process production order in a real-time environment accurately and reduce potential waste due to uncontrolled overproduction”.

Quality Assurance Manager with 10 years of Experience: “MES is a novel in its entirety and with this system, it is possible to have control over what is going on at every stage of production like how materials come in and how they are transformed into products”.

Pharmaceutical Technologist with 10 years of Experience: “I think MES will be a good development and should work hand in hand with enterprise resource planning (ERP) with the way this assist in managing inventories”.

It has been maintained in the plethora of literature that cloud computing and big data analytics are at the heart of digital transformation, and with an understanding of the enormous amount of data that are being generated in pharma operations (Manzano and Langer, 2018), the respondents were asked to share their understanding of the potentials of big data analytics in their industrial environment (**Interview Question 10**). Quoted responses are as follows

Pharmaceutical Technologist with 10 years of Experience: “In a typical pharma environment, I believe big data analytics have an important role as it will be possible to gather and process information faster and more efficiently”.

Validation Manager with 12 years of Experience: “Data analytics is a development that is widely considered not only in pharma environment but in all

parastatals and I see big data analytic platforms playing a huge role in Nigerian pharma environment in terms of optimizing process”.

R&D Scientist with 13 years of Experience: “Having a platform that can generate and handle a large amount of data at a low amount of time comes with positive impact because pharma process generates large data that can be used to improved operation”.

Other resourceful respondents engaged in the interviews explained that due to the enormous amount of data generated from various operations including R&D activities, manufacturing process data, equipment performance data which are becoming too complex to handle, big data analytics hold the key in utilizing information as a production resource, and taking a predictive approach to equipment maintenance and hence achieving excellent operation. Opinions that are quoted according are as follows:

Quality Assurance Manager with 10 years of Experience: “Data coming from R&D and manufacturing processes are becoming more exorbitant to handle and if I may say are underutilized and with data now becoming inexhaustible production resources, imagine having a platform which can handle the large volume of data without issue, I believe big data analytics will be of advantage in a pharma environment”.

Operation Manager with 15 years of Experience: “Big data along with AI-powered systems are an integral element in achieving pharma 4.0 and aside from the issue of cybersecurity, they are of important application in all areas of pharma operations say product development, manufacturing operation, or maintenance of equipment with predictive analysis”

All respondents were also asked to share their opinion on the novelty of the internet of things (IoT), augmented reality as well as computerized management systems (**Interview Q11**). It is discerned from their pattern of responses that IoTs and augmented have a relevant role to play in the pharma shopfloor environment and are important tools that are to be considered in digital transformation

Operation Manager with 15 years of Experience: “These are other elements of I4.0 that are to be imbibed because developments like Industrial Internet of Things and smart sensors will enable improved connectivity and sharing of data and information across board and among machines without any notable hitch”

Quality Assurance Manager with 10 years of Experience: “All these technologies which have found significant application in Nigeria but are novel because, with IoTs, it is possible to achieve synchronization like having all machines effectively connected and with augmented reality, the possibility to prognoses where things can go wrong is an added advantage” .

Validation Manager with 12 years of Experience: “I believe IoT in any pharma manufacturing environment will come with better control of manufacturing processes as well as improved supply chain management activities”.

Pharmaceutical Technologist with 10 years of Experience: “Augmented reality will have a role to play before product launch and when a particular batch has a defect, it will be easy to determine this in eliminating the issue of any potential product return”.

4.3.5. Cost-Efficiency, Improved Product Quality and Speed to Market

With pharma 4.0 being pinpointed as an operating model and the rejuvenating impact of digital transformation on existing pharma business model been explicitly described in other literature (Landwehr, 2015; Ehrhardt and Behner, 2016), the experts from the different pharma companies engaged in this study were asked to discuss how pharma 4.0 is forming part of their corporate and business strategy (**Interview Question 12**). The respondents discussed pharma 4.0 as a model and strategy which pharma companies in Nigeria should fully embrace so as not to be left behind as an individual corporate organization and in taking the industry to a new height as a collective group.

Quoted responses are as follow:

Operation Manager with 15 years of Experience: “The future is already here and we are realizing the role that data and information is playing in manufacturing

operation and the reality is that the business who adapt to the changing game of I4.0 and pharma 4.0 will be around for the next revolution and those who don't might be swept aside"

Quality Assurance Manager with 10 years of Experience: "I will say digital transformation is a model itself which I will say everyone should turn their focus on even though pharma is highly rigid when it comes to making changes but with development here and there, I believe it is high time to move along the norm"

Validation Manager with 12 years of Experience: "In the future, pharma will be left with no choice than to accept the full digital transformation and it is high time everybody embraces Industry 4.0 and Pharma 4.0 to make this industry top-notch"

R&D Scientist with 13 years of Experience: "The world is changing and one cannot afford to be left behind and it (digital transformation) doesn't have to be in manufacturing area alone but all aspect of pharma environment that can be transformed"

All the respondents were also asked to give their opinion on how digital transformation will impact the current business model based on the fact that Nigerian pharmaceutical companies are generally secondary drug-producing companies whose business model is based on speed to market and price as established in the work of Olubunmi (2015) (**Interview Question 13**). The benefits of this initiative cited by respondents include cost reduction, production efficiency, and improved quality compliance in manufacturing operations.

Quoted responses are as follows

Quality Assurance Manager with 10 years of Experience: "With digital transformation, we can achieve a lot of things like cost efficiency which will happen once idle physical assets are eliminated as a result of a process that can be operated in a virtual space is made to go virtual and build speed and efficiency into manufacturing process which I believe is essential in outperforming competitors in terms of who gets product first to the market"

R&D Scientist with 13 years of Experience: "With digital transformation, it is possible to reduce workload, cut down cost and getting more efficient output".

Operation Manager with 15 years of Experience: “I see digital transformation doing more good than harm because price and speed are an important element for pharma companies and it is important to lower the operating cost and improve speed without compromising quality and I see digital transformation achieving this”.

Respondents were asked to discuss and suggest the aspect of pharma operations and processes in which they believe digital transformation is imminent for Nigerian pharma companies to invest so as to be more competitive (**Interview Question 14**). Respondents discussed investment in the area of product testing on the shop floor due to issues of the batch defect and processing error; data collection and utilization as well as supply chain and warehouse functions due to the challenges experienced during the pandemic. Quoted responses are as follows:

Quality Assurance Manager with 10 years of Experience: “Product return and recall are challenges due to processing method and I believe the investment is important here and also in the area of data utilization, investment in the cyber-physical system will lead to improved data collection, processing, and utilization to make an informed decision because data is like a right-hand man for any decision-maker and with it you can always know the next thing to do”.

Operation Manager with 15 years of Experience: “Investment will be welcomed in the manufacturing area and also integrating the supply chain so as to always improved the material flow”

Validation Manager with 12 years of Experience: “The supply chain requires an imminent need of digital transformation because during the pandemic a lot of pharma companies struggled in achieving excellent operation”

4.3.6. Knowledge Gap, Lack of Funds and Poor Infrastructures—Barriers in Digital Transformation

While respondents discussed the endless potentials and possibilities of digital transformation in the Nigerian pharma industry environment, and as well discussing their inclination towards the full embrace of the pharma 4.0 concept, they were asked quizzed if there is any potential general or industry-specific barrier and challenges in achieving this (**Interview Question 15**). From the pattern of opinion shared by respondents across the series of interviews conducted, barriers to digital transformation in the Nigerian pharma industry were discussed in terms of infrastructural challenges in the areas of energy and power needed in driving industrial operations; a significant gap in knowledge when it comes to core pharma manufacturing operations and how to implement industry 4.0/pharma 4.0 initiatives; lack of funds and resources in implementing resource-intensive digital technologies were the leading barriers and challenges cited by respondents. Some of the responses that were quoted are as follows

Validation Manager with 12 years of Experience: “There are a lot of challenges to be honest and a lot of people lack knowledge about the industry 4.0 and pharma 4.0 and when you’re setting up a system, experience and expertise are required to get it running but there’s limited knowledge out there”.

Quality Assurance Manager with 10 years of Experience: “Knowledge gap infrastructure challenges, lack of funds and resources are part of the challenges that most of these privately-owned companies faced”.

Pharmaceutical Technologist with 10 years of Experience: “Lack of expertise is a leading challenge because we don’t have many people who understand the core pharma manufacturing which I believe has not been explored and it is hard to delve into something so sensitive”.

Another respondent also discussed the issue of cybersecurity as well as regulatory hurdles to constitute the host of challenges in the Nigerian pharma industry environment when it comes to achieving smart manufacturing. An apt response was quoted as follows:

Operation Manager with 15 years of Experience: “Data security in a real-time environment, as well as a regulatory hurdle, is another challenge because pharma

environment is a sensitive one and going through the process of validation makes digital transformation, not something a company can implement here on its own and in in the Nigerian pharma environment which still lacks knowledge”.

The respondents were asked to discuss the various strategies or approaches through which some of these barriers and challenges in achieving digital transformation can be overcome (**Interview Question 16**). Initiatives aimed at cultivating a developing digital mindset, foreign direct investment in pharma operations, fixing infrastructural challenges as well as bridging the gap in knowledge were discussed to be of importance in overcoming barriers to effective and full digital transformation in the Nigerian pharma environment. Quoted responses are as follows

Operation Manager with 15 years of Experience: “We need more knowledge and exposure at the industry level, investment at the business level and government playing their part to fix the infrastructure problems in the industry”

Validation Manager with 12 years of Experience: “Awareness, adequate training and having digital mindset is integral in achieving full digital transformation”.

Quality Assurance Manager with 10 years of Experience: “Digitalization is not just all about investing billions of dollars in digital technologies, machines, and tools, it (digital transformation) is a mindset that everyone should first understand the need to embrace it”

4.4. Discussion of Research Findings

The various findings made in this research enable a robust understanding of the relevance and role of digital transformation in the Nigerian pharmaceutical industry manufacturing process to be achieved. The various roles and advantages can be summed up in two major areas including excellent manufacturing operations at the shop floor and improved business excellence at the market level.

1. Nigerian Pharma Manufacturing and Digital Transformation

Pharmaceutical industry experts including Minero and Augeri (2018) and Manzano and Langer (2018) as well as industry 4.0/pharma 4.0 critiques such as Borangui et al (2020) and Ehrhardt and Behner (2016) have all discussed the positive influence of digital transformation and the need to be more operationally efficient in pharma manufacturing operations. It is found in this study that digital transformation has a novel role to play in the various product manufacturing operations of pharmaceutical companies in Nigeria.

The various potentials of digital transformation shared by the experts engaged in this study correlates with what others have been discussed and reviewed in the literature. This study broadly summed up the role of digital transformation in the Nigerian pharma industry as an enabler of manufacturing/operational excellence in an environment in which the approach to product development and manufacturing are still based on the conventional and traditional methods such as the use of papers to relay information and manage various shop floor activities that are the dominant feature that pharmaceutical industry, in general, has been traditionally renowned for (Gaertner, 2015). In this context, the use of less sophisticated tools in the areas of product quality testing was found to be the dominant technology as compared to the use of advanced digital tools such as the process analyzers and chemometric tools in the advanced world which have been discussed in the work of Aksu and Yeğen (2021) as enabling tool in building quality into products and reducing process variability in an ongoing manufacturing operation.

Also, no major production management and control system (e.g. manufacturing execution system), equipment management system (e.g. computerized maintenance management system) was found to be of current use and application in the pharma environment of most companies in Nigeria and possibly the industry at large as the experts in the industry who were engaged in the

study gave a holistic assessment of the current level of digital technologies used in the Nigerian pharmaceutical industry environment which makes it convenient to assert that Nigerian pharma industry is “immature” as pharma companies are realizing the need to be digitally transformed. This assertion made is even more robust when consideration is given to the thought of Ehrhardt, and Behner (2016) who had explained that the new wave of the industrial revolution in any pharma environment will occur in the area of product manufacturing processes

The endless potentials and possibilities that digital transformation and its enabling tools like the PAT tools, Industrial internet of things, augmented reality, cloud computing, big data analytics use in a digitally transformed pharma environment have been discussed in the literature (Manzano and Langer, 2018; Aksu and Yeğen, 2021) and based on the abstractified knowledge of the respondents engaged who discussed how an error in processing, batch defect, and various operational bottlenecks can be addressed with digital technologies, an assertion made in this study is that digital transformation (if achieved) comes with significant potential for Nigerian pharma companies to achieve “Operational Excellence” whose elements include but not limited to:

- Product quality enhancement and improved compliance
- Reduced downtime due to machine breakdown or stop-gap in operations
- Elimination of waste
- Improved organic synthesis of man, physical asset, and material through improved connectivity
- Better handling and utilization of pharma operation and manufacturing data

2. Impact of Digital Transformation on Nigerian pharma industry Business Model

Experts including Bjorkdarhl (2020), researchers including Landwehr (2015), and other scholars have as well discussed the impact of digital transformation on business models and strategies in fostering competitive advantage. In the pharma industry-specific environment, the role of digital transformation on the business model has been described in terms of moving from the popular production of the generic product to the development of personalized pharmaceutical products such as wearable devices that can be embedded with specific sensors and hence overhauling the mass production principle to customized production (Landwehr,

2015; Manzano and Langer; 2018). In the Nigerian pharmaceutical industry-specific landscape in which secondary production of drugs still remains to be the prevailing business model with drug price and speed being an important element, it is found out and concluded that digital transformation will impact and improve the business model and strategies used in product manufacture and product marketing by facilitating a way to achieve cost efficiency and speed to market (based on faster processing that could be achieved through continuous production instead of a batch) while improving the quality (i.e. reduced error rate, and decreased product defect).

While it is found out in this study that ICT tools have found application in the area of product marketing (i.e. sales channel) in the Nigerian pharma environment, the areas of product manufacturing (product quality testing), and shop floor activities (data collection/utilization and equipment maintenance) well as the integration of cross-functional supply chain are of in need of imminent application of digital technologies so as to achieve business excellence. In the same vein and despite the pharmaceutical industry being traditionally a rigid industry and with the flexibility conferred by digital transformation, it was found out that the pharma companies in Nigeria are not afraid to make changes as experts in the industry maintained that the companies are inclining positively towards pharma 4.0 model and are incorporating its elements into their existing business model and strategy through:

- Developing and cultivating digital mindset as corporate culture and incorporating digital tools into their business strategy
- Restructuring and Investing in the areas of information technology

3. Barriers in Digital Transformation

With the findings made in this study that the Nigerian pharmaceutical is essentially digitally immature despite the endless potentials of digital transformation in contributing to operational and business excellence for Nigerian companies can achieve digital maturity by embracing the pharma 4.0 (widely regarded as the future of pharmaceutical manufacturing) and industry 4.0 elements, this study found out factors including knowledge gap, lack of expertise, infrastructure challenges, lack of funds as well as regulatory hurdles to be among the leading challenges facing Nigerian pharma companies in the industry when trying to keep up with the pace of industrial change occurring in the advanced world. Awareness about the need to embrace the pharma 4.0

model, organizations cultivating the digital mindset and instilling its principle in the workforce, industrial training, and exposure as well as sufficient investment are found to be integral in achieving digital transformation in the Nigerian pharma manufacturing environment which will thus make the industry to be topnotch at large.

CHAPTER FIVE: Concluding Thoughts on the Contribution of this Research, its Limitation and Suggestions for Future Research

5.1. Implication of Findings for the Research Questions

The findings made in the scope of the research enabled the various research questions stated to be answered and the objectives to be achieved. By achieving an understanding of digital transformation as a technology-driven initiative aimed at improving business processes, and how it can contribute to operational excellence in a manufacturing environment, the research is able to answer the first stated research question. By defining a digitally matured industry as that which is virtually making use of advanced digital technologies and initiatives in its operation, the research question about the level of digital maturity in the Nigerian pharma is answered through findings made that the industry is digitally immature as most of the manufacturing processes are still based on the traditional approach. Hence research objective 1 is achieved

Also, the findings made that pharma industries are cultivating a digital mindset and investing in information systems and technology-enabled the study to answer the question of how industry leaders are responding to the new pace of industrialization that has to do with the use of advanced technologies in manufacturing operations. This as well enabled the study to realize the second stated research objective.

By establishing that digital technologies are of important relevant application in the areas of product development, and various shop floor activities which can be digitally-driven and improved with the use of systems based on cloud computing principles, augmented reality, 3-D printing amongst a host of other advanced analysis tools (PAT tools) enables reduced variability and eliminate defect in on-going operations, the third research objectives are as well achieved and the various stated research questions are answered. The study conveniently asserts that digital transformation and tools that are relevant in the pharma environment will achieve goals that are linked to operational excellence.

As this study found out that Nigerian pharmaceutical companies are seriously considering the use of advanced technologies in driving their operations and operational bottleneck stemming from equipment downtime, production defect as well digitization of cross-functional supply chain functions, a convenient assertion made is that digital transformation will contribute to production cost optimization, process efficiency and speed to market. Hence the

impact of digital transformation on a business model and strategy of pharma companies in Nigeria is described as enabling faster production at reduced production cost and as such the fourth research objective is achieved and the sets of accompanying questions were answered.

By classifying knowledge gap, regulatory hurdles, the characteristic poor infrastructures which affect the general industrial sector in Nigeria, lack of expertise as well as lack of funds as dominant challenges in achieving digital transformation in the Nigerian pharmaceutical manufacturing, the fifth research objective is achieved and the research question stated underneath this objective is answered as the assertion made here is that regulatory hurdle, knowledge gap and lack of expertise are industry-specific barrier and challenges while infrastructure problems and lack of funds are challenges that are synonymous to all and sundry.

The sixth objective is as well achieved as various practical recommendations are made based on the findings made that awareness about the need to embrace the new norms of pharma 4.0, improved industry exposure and significant investment, etc. are essential in overcoming barriers to digital transformation. The research question is as well answered

5.2 Contributions and Limitations of the Research

By studying the concept of digital transformation and establishing its relevance in the pharmaceutical industry environment, this study contributed to the robustness of literature by bridging the identified knowledge gap and providing insight for the future research study. In this regard, the study successfully accounted for a wide array of the benefits conferred by digital transformation and its enabling tools. The theoretical contribution of the study is reflected in the series of the advantages that can be realized in the pharmaceutical industry-specific environment when digital tools are adopted while the practical contributions of the study are reflected in the various practicable initiatives which can be followed when digitalizing pharma manufacturing environment.

5.3 Recommendation for Practice

Technology is a mover of change and industrial revolutions will continue to occur. The pharmaceutical industry cannot afford to be left behind in the game as data and information is becoming a vital production resource in this current knowledge-based system. Digitalization holds the key and its enabling tools are of relevance in achieving operational and business excellence. While the pharmaceutical industry operates in a sensitive environment and is hence

inherently rigid, it is as well not afraid to make changes as well. A testament to this is the introduction of pharma 4.0 (which industries in the advanced world have been embracing) as an industry-specific variant of industry 4.0. While pharmaceutical industry development varies across regions and with the pharma 4.0 model and industry 4.0 concept still green to the Nigerian environment, it is important that the Nigerian pharmaceutical industry should move along with the trend and tends toward smart manufacturing through

1. A digital mindset should be cultivated from the upstream level and instilled to the downstream by pharma companies in Nigeria and other regions alike who are yet to embrace the pharma 4.0 concept and hence adjust to the changing realities.
2. Knowledge and expertise are highly important in achieving effective digital transformation in a sensitive industry like a pharmaceutical industry that solely exists to contribute to improved quality of life. Digital transformation entails making changing changes to existing processes and technologies which have been validated. Hence digital transformation of any relevant activity which has to do with product development and manufacturing should only be carried out based on informed knowledge, a significant level of expertise, and compliance with regulatory protocols
3. Pharmaceutical companies in Nigeria are specifically urged to invest more in the area of information systems, adopt digital technologies and use them in relevant areas which can contribute to operational excellence

5.4. Recommendation for Future Research

Within the scope of this research, an understanding of the relevance and potential role of digital transformation in the Nigerian pharmaceutical industry environment has been studied and accounted for. Given the wide array of the potentials in the use and application of digital technologies in manufacturing processes pharma manufacturing operations and with this study having confirmed, from the experienced experts in the Nigerian pharmaceutical industry, that digital transformation is far from being achieved, the following suggestions are made for future research

1. A quantitative research archetype of this study is recommended to be conducted in any future research study so as to make some of the findings made in this study to be more generalizable based on collected numerical facts and figures

2. A discovery made in this study is that there is still a dearth of knowledge on the pharmaceutical manufacturing processes in the Nigerian environment as no research literature detailing pharmaceutical manufacturing processes could be found and hence making it hard in the present study to study specific pharma manufacturing process can be imminently digitalized in a company-specific environment. With this study having found three areas including product quality testing, equipment maintenance, and data collection and utilization as areas in which digital transformation are of imminent, it is suggested that future researchers should explore the potentials of specific digital tools such as PAT tools in the area of quality testing; Big data analytics and cloud computing in the aspect of pharma manufacturing data collection and utilization; use of computerized maintenance management systems in improving pharma manufacturing processes in the Nigerian environment

5.5. Final Conclusion and Reflections

In this dissertation, the relevance and role of digital transformation in pharmaceutical manufacturing operation was explored. The study established that digital transformation has the potential to contribute to operational excellence at the manufacturing level and business excellence at the market level. Cultivating a digital mindset, bridging the knowledge gap, and investing in information technology and systems were established as novel initiatives towards achieving digital transformation in a typical Nigerian pharmaceutical environment that is still digitally immature.

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